



**AUG 27 1996**

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**Summary of Safety and Effectiveness  
Statak Soft Tissue Attachment Device**

**K962397**

- **Submitted by:**  
  
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- **Date:**  
  
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- **Trade Name:**  
  
*Statak®* Soft Tissue Attachment Device
- **Common Name:**  
  
Soft Tissue Anchor
- **Classification Name:**  
  
21 CFR 888.3040, Smooth or Threaded Metallic Bone Fixation Fastener
- **Predicate Devices:**
  - *Statak®* Soft Tissue Attachment Device, K926384
  - GII Anchor System, manufactured by Mitek Surgical Products, Inc., K953877
  - Mini Anchor, manufactured by Mitek Surgical Products, Inc., K930892 and K904436



- **Device Description:**

The *Statak* Soft Tissue Attachment Device anchor has a diameter of 2.5 mm, is self-tapping, self-drilling, and fully threaded. A double strand, braided, nonabsorbable Size No. 2-0 suture is attached to an eyelet at the end of the anchor. A disposable driver which can be attached to a powered handpiece holds the excess suture and delivers the anchor directly into the bone. When the driver is removed, the suture strands are left emerging from the bone. The strands are then used to secure the soft tissue to the bone.

- **Intended Use:**

The devices are intended for soft tissue-to-bone suture fixation for the following indications:

Shoulder

- Bankart lesion repairs
- SLAP lesion repairs
- Acromio-clavicular separation repairs
- Rotator cuff tear repairs
- Capsular shift or capsulolabral reconstructions
- Biceps tenodesis
- Deltoid repairs

Foot and Ankle

- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Hallus valgus reconstructions

Elbow, Wrist, and Hand

- Scapholunate ligament reconstructions
- Ulnar or radial collateral ligament reconstructions
- Tennis elbow repair
- Biceps tendon reattachment

Knee

- Extra-capsular repairs:

- Medial collateral ligament
- Lateral collateral ligament
- Posterior oblique ligament
- Iliotibial band tenodesis
- Patellar tendon repairs

- **Performance Data:**

The *Statak* Soft Tissue Attachment Device was tested by tension loading the suture in the hand bones of cadaver specimens, with the results compared to a suture-only tenodesis procedure in similar bone. The *Statak* Soft Tissue Attachment Device performed as well as the suture-only tenodesis procedure.

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